



K060425

JUL 12 2006

510(k) Summary
ArthroCare Corporation
Parallax® Acrylic Resin Cartridge with TRACERS-Ta

General Information

Manufacturer: ArthroCare, Corporation
680 Vaqueros Avenue
Sunnyvale, CA 94085

Establishment Registration Number: 2951580

Contact Person: Valerie Defiesta-Ng
Director, Regulatory Affairs

Date Prepared: February 15, 2006

Device Description

Classification: PMMA Bone Cement: Class II per 21 CFR
888.3027

Trade Name: Parallax® Acrylic Resin Cartridge with
TRACERS-Ta

Device Code: NDN

Generic/Common Name: Bone Cement

Predicate Device

Parallax® Acrylic Resin with TRACERS®-Ta	K050864
Parallax® Acrylic Resin Cartridge with TRACERS®	K053180

Intended Use

Parallax® Acrylic Resin Cartridge with TRACERS-Ta is intended for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Product Description

Parallax® Acrylic Resin Cartridge with TRACERS-Ta is an opacified polymethylmethacrylate bone cement.

Substantial Equivalence

The subject device is substantially equivalent to the ArthroCare Parallax Acrylic Resin with TRACERS-Ta (K050864) and the Parallax Acrylic Resin Cartridge with TRACERS (K053180).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Arthrocare Corporation, Inc.
% Ms. Valerie Defiesta-Ng
Director of Regulatory Affairs
680 Vaqueros Avenue
Sunnyvale, California 94085-3523

JUL 12 2006

Re: K060425

Trade/Device Name: Parallax Acrylic Resin Cartridge with Tracers[®] - Ta
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: June 1, 2006
Received: June 2, 2006

Dear Ms. Defiesta-Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

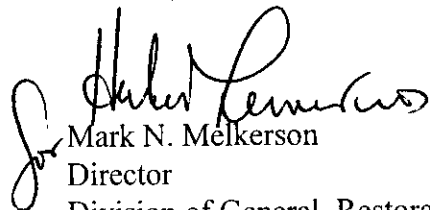
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Valerie Defiesta-Ng

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: Parallax[®] Acrylic Resin Cartridge with TRACERS-Ta

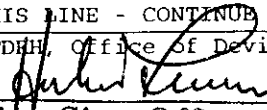
Indications for Use:

Parallax[®] Acrylic Resin Cartridge with TRACERS-Ta is intended for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K060425